

Remarks/Arguments:

STATUS OF THE CLAIMS

Claims 1-3 and 8-14 are pending.

Claim 1 has been amended to correct a typographical error.

Claim 10 has been amended to delete the phrase "or solvate".

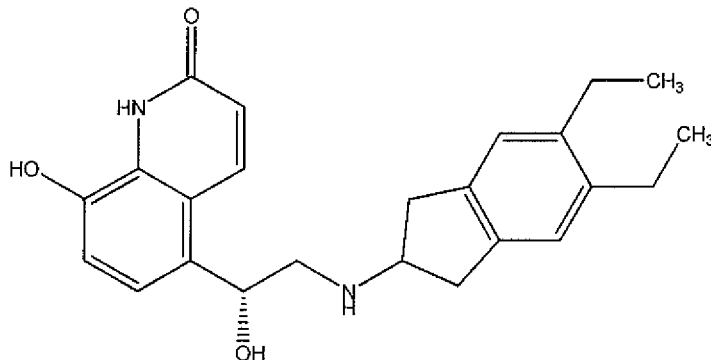
SPECIFICATION

The Examiner has objected to the disclosure because it is missing a "Brief Description of the Drawings." Applicant has amended the specification to include a section titled "Brief Description of the Drawings". Applicant respectfully requests that the present objection be withdrawn.

The Examiner has objected to the use of trademarks "Viozan" and "Ariflo" because the terms are not capitalized and accompanied by their generic terminology. Applicant has amended the specification to capitalize these terms and prove their generic terminology. Applicant respectfully requests that the present objection be withdrawn.

REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH

Claim 10 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for pharmaceutically acceptable salts of



the specification does not reasonably provide for solvates of said compound. Applicant respectfully traverses.

Applicant has amended claim 10 to remove the phrase "or solvate". Applicant respectfully requests that the present rejection be withdrawn.

REJECTION BASED ON 35 U.S.C. 102

Claims 2, 3 and 8-13 are rejected under 35 U.S.C. 102 as being anticipated by Cuenoud et al. (WO 02/00679). The Examiner states that Cuenoud teaches a genus of compounds of formula I. The Examiner also notes that crystalline forms do not exist in solution and, thus, the claimed composition will be identical to that of the prior art. Applicant respectfully traverses.

It is axiomatic that once an independent claim is allowed, claims dependent on the allowed independent claim are also allowable because dependent claims, by definition, are more narrow than the claim(s) from which they depend. See MPEP 608.01 "Claims in dependent form shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim." Here, independent claim 1 is not anticipated by Cuenoud. Claims 2, 3 and 8-13 depend from claim 1. Accordingly, these claims cannot be anticipated by Cuenoud.

The Examiner's observation that crystalline forms do not exist in solution is moot. The instant claims are directed to a compound, a composition comprising the compound, a method of using the compound and a method of preparing the compound. None of these embodiments are directed to a solution comprising the compound.

Finally, in order to anticipate a claim under 35 U.S.C. 102, all of the limitations of the claim must be disclosed in a single prior art reference. MPEP 2131; Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987). As the Examiner acknowledges, the instant claims differ from Cuenoud in the recitation of a "crystal form B" and all of its claimed characteristics as described in claim 1. Office Action Page 9. Cuenoud simply discloses the compound of formula I and fails to disclose the existence of polymorphs for the compound of formula I. Thus, since all of the claim limitations are not disclosed, the claims cannot be anticipated.

For at least these reasons, Applicant respectfully requests that this rejection be withdrawn.

REJECTION BASED ON 35 U.S.C. 103

Claims 1-3 and 8-14 are rejected under 35 U.S.C. 103 as being unpatentable over Cuenoud. The Examiner states that the instant claims differ from Cuenoud in the recitation of crystal form B and a method of preparing the claimed crystal form B. The Examiner states that purification of a compound by the production of a crystal form is well known and that Cuenoud teaches the production of a crystalline form of the claimed compound. Applicant respectfully traverses.

The issue of obviousness is a question of law that must be resolved on the basis of the Graham factual inquiries. To support obviousness of the claimed invention "either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teach of the references." MPEP 706.02(j). Suitable rationales for a finding of obviousness include A) Combining prior art elements according to known methods to yield predictable results; B) Simple substitution of one known element for another to obtain predictable results; C) Use of known techniques to improve similar devices, methods or products in the same way; D) Applying a known technique to a known device, method or product ready for improvement to yield predictable results; E) "Obvious to try" - choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; F) known work in one field of endeavor may prompt variations of it for use in the same or different field based on design incentives or other market forces if the variations would have been predictable to the skilled artisan; and G) A teaching, suggestion or motivation in the prior art

would have led the skilled artisan to modify the reference or combine the teaching to make the claimed invention. Federal Register, Vol. 72, No. 195, Oct. 10, 2007, Notices.

As the Examiner acknowledges, "[t]he instant claims differ [from Cuenoud] in the recitation of a crystal form B and a method of preparing the claimed crystal form B." Office Action Page 9. Likewise, Cuenoud does not provide any suggestion of crystal form B nor any process for making a particular crystal polymorph. The Examiner states that Cuenoud teaches the formation of "a" crystalline form of the compound of formula I. Yet, the crystalline form taught by Cuenoud is crystalline form A, not form B. Cuenoud's "Method B2" generates the "crude product crystallized" from "isopropanol." The instant specification teaches that crystallizing from isopropanol generates form A. More important, the specification teaches that crystallizing from ethanol generates the claimed form B. As seen in Figures 3, 4 and 5 of the specification, regardless of temperature, the crystallization from isopropanol always forms crystal form A and crystallization from ethanol always forms crystal form B. Clearly then, Cuenoud cannot demonstrate the crystal form B, nor its preparation method, to be a "predictable" result as required.

Moreover, the Examiner's reliance on Ex parte Hartop for the proposition that purification of a known compound to a crystalline form is well within the skill of one in the art is misplaced. The BPAI has repeatedly criticized the invocation of this per se rule.

The examiner apparently would invoke a per se rule of obviousness, viz., that merely changing the form, purity, or another characteristic of an old product, the utility remaining the same as that for the old product, does not render the claimed product patentable. See Ex parte Hartop ... We disagree.

Second, the principle of law enunciated in Ex parte Hartop, 139 USPQ 525, 527 (Bd. App. 1962) has been substantially **discredited** in In re Cofer, 354 F.2d 664, 667-68, 148 USPQ 268, 270-71 (CCPA). See Ex parte Portmann et al., Appeal 2003-1199, Nov. 17, 2003; See also Ex parte Andrews et al., Appeal 2002-0941, Sept. 25, 2003. [emphasis added].

When considering the obviousness of polymorphs of a known compound in view of the prior art reciting the known compound, the BPAI has consistently found that polymorphs are patentably non-obvious. For example, in Ex parte Andrews, the applicants claimed a polymorph of a known compound. The claims were rejected as being obvious over the prior art disclosing the compound, but "silent" as to crystalline forms. The Board reversed the obviousness rejection

stating there was no explanation how a person skilled in the art would have been led from here to there, i.e. the general compound to the recited polymorph.

Even more telling is Ex parte Reguri, Appeal 2007-0313, Sept 6, 2007, in which the applicants claimed a new polymorph of a known compound wherein the compound had other known polymorph forms. The claims were rejected as being obvious over the prior art compound and other known polymorph forms. The Board reversed the obviousness rejection stating the knowledge of other known polymorph forms and routine recrystallization methods "would not necessarily lead to the claimed crystalline forms, however."

Here, the Examiner has rejected the claimed polymorph crystal form B of a known compound in view of Cuenoud's disclosure of the known compound and polymorph crystal form A. As clearly indicated by the BPAI's decisions, the Examiner has not established a prima facie case of obviousness because one skilled in the art would have no reasonable expectation of successfully producing crystal form B in view of Cuenoud.

For at least these reasons, Applicant respectfully requests that this rejection be withdrawn.

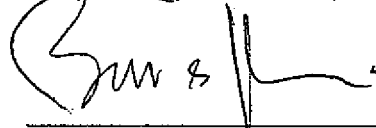
CONCLUSION

Applicant respectfully submits that the claims are in a condition for allowance. Prompt consideration and allowance are therefore respectfully requested.

Applicant requests that a one-month extension fee of **\$130.00** be charged to **Deposit Account No. 50-3570**. In the event that any fee has been inadvertently overlooked and is required, the Commissioner is hereby authorized to charge any required fee or credit any overpayment to **Deposit Account No. 50-3570**.

If the Examiner determines that the application is not in condition for allowance, it is respectfully requested that the Examiner contact the Applicant's undersigned counsel at the telephone number indicated below to arrange for an interview to expedite the disposition of the application.

Respectfully submitted,



Basil S. Krikelis
Registration No. 41,129
Patrick A. Walker III, Ph.D.
Registration No. 58,734
Attorney for Applicant(s)

Dated: July 1, 2009

BSK/rls

McCarter & English, LLP
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, DE 19801
Phone: (302) 984-6300
Fax: (302) 984-6399